

Docket No.: 086016-0034

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Tara BIELSKI, et al.

Application No.: 10/800,031

Customer No.: 20277

Filed: March 15, 2004

Confirmation No.: 6868

Group Art Unit: 1615

Examiner: Bethany BARIHAM

Title: NOVEL ORALLY ADMINISTRABLE FORMULATION OF NITROFURANTOIN  
AND A METHOD FOR PREPARING SAID FORMULATION

**REPLY BRIEF**

Mail Stop Appeal Brief - Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. § 41.41, the following remarks are respectfully submitted in response to issues raised in the Examiner's Answer dated November 28, 2011.

The **Status of the Claims** is on page 2 of this paper.

The **Grounds of Rejection to be Reviewed** are on page 3 of this paper.

**Remarks and Arguments** begin on page 4 of this paper.

**STATUS OF THE CLAIMS**

Claims 1-60 and 66 are pending. Claims 1-60 and 66 have been rejected and are on appeal. Claims 61-65 have been withdrawn.

**GROUND OF REJECTION TO BE REVIEWED ON APPEAL**

Whether claims 1-60 and 66 are obvious under 35 U.S.C. § 103(a) over U.S. Patent No. 4,772,473 in view of U.S. Patent Publication No. 2003/0180359 or U.S. Patent No. 4,792,452 and U.S. Patent No. 5,415,871.

## **REMARKS**

The claims on appeal are directed to compositions and methods for preparing an oral formulation comprising a first controlled release component comprising nitrofurantoin monohydrate, sodium alginate, alginic acid, and hypromellose; and a second immediate release component comprising macrocrystalline nitrofurantoin.

### **I. Prior art must be considered for what it teaches as a whole**

The primary reference cited by the Examiner in the rejection under 35 U.S.C. § 103(a) is U.S. Patent No. 4,772,473. See Office Action dated November 9, 2010, p. 3. Appellants argued that one of ordinary skill in the art would not have substituted sustained release excipient ingredients taught to be “necessary” in the ‘473 patent (i.e., polyvinylpyrrolidone and carboxyvinylpolymer) with other ingredients (i.e., sodium alginate, alginic acid, and hypromellose) in order to arrive at the instantly claimed formulation. See Appeal Brief, p. 14-17. The Examiner downplays or dismisses this express teaching: “The Examiner respectfully points out that ‘473 is ... not [relied upon] for its teaching of the instant claimed sustained release excipients.” Examiner’s Answer, p. 9. However, the Federal Circuit has held that: “the prior art must be considered as a whole for what it teaches.” *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1166 (Fed. Cir. 2006); MPEP 2142.01 (citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert denied*, 469 U.S. 851 (1984)). Here, the ‘473 patent teaches that certain ingredients are “necessary.” See, ‘473 patent, col. 3, ll. 67-68; col. 4, l. 42; col. 6, l. 34, 37-39; col. 7, l. 16, 18-20. It was improper for the Examiner to ignore this teaching in order to state that one of ordinary skill in the art would not have employed the “necessary” ingredients and, instead, selected other ingredients to arrive at the instantly claimed formulation.

## II. No basis to state that “necessary” refers to functions and not to compounds

The Examiner states that the term “necessary” in the ‘473 patent refers to the function of certain ingredients, and not to the compounds themselves. Examiner’s Answer, p. 11. As an alternative to ignoring the ‘473 patent’s teaching that certain ingredients are “necessary” (see I, above), this position would justify substituting these ingredients in order to arrive at the instantly claimed formulation. This approach should fail because there is no factual basis for it. *KSR International Co. v. Teleflex Inc.*, 500 U.S. 398, 418 (2007) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). The ‘473 patent does not disclose that “necessary” refers to a function, which would encompass a universe of interchangeable compounds (thereby justifying the Examiner’s position that the “necessary” ingredients are taught to be replaceable). There is no factual underpinning for the Examiner’s position.

Appellants’ position that “necessary” refers to certain, specific ingredients (compounds) is amply supported by the ‘473 specification:

- “The necessary ... ingredients are described below.” ‘473 patent, col. 3, ll. 67-68 (emphasis added);
- “[P]olyvinylpyrrolidone is a necessary ingredient ...” ‘473 patent, col. 6, ll. 36-39;

- “Without the presence of polyvinylpyrrolidone in the particulate mixture, either a cohesive mass does not form, or any mass that does form does not have sufficient structure to provide the desired sustained release.” ‘473 patent, col. 6, ll. 63-67;
- “Carboxyvinylpolymer is another necessary ingredient ...” ‘473 patent, col. 7, ll. 18-20; and
- “For the combination sustained release/rapid release pharmaceutical capsules of the present invention, necessary ingredients are the nitrofurantoin, polyvinylpyrrolidone, and carboxyvinylpolymer ...” ‘473 patent, col. 8, ll. 44-48.

For the reasons stated above, and contrary to the Examiner, the ‘473 patent teaches that specific compounds are “necessary.” The ‘473 patent does not teach that certain functions are necessary, such that any number of compounds may be suitably employed. Thus, one of ordinary skill in the art would not have substituted “necessary” compounds to arrive at the instant invention as urged by the Examiner.

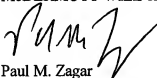
In accordance with the reasons stated above and in the Appeal Brief, one of ordinary skill in the art would not have replaced the “necessary” ingredients polyvinylpyrrolidone and carboxyvinylpolymer with sodium alginate, alginic acid, and hypromellose in order to arrive at the instantly claimed formulation.

**Conclusion**

Based upon the arguments above, appellants respectfully request that the Honorable Board reverse the Examiner's obvious rejections, and allow claims 1-60 and 66.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP

A handwritten signature in black ink, appearing to read 'P. M. Zagar', with a large, sweeping checkmark-like flourish extending from the end of the signature.

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